

PCTWORLD INTELLECT
Inte

INTERNATIONAL APPLICATION PUBLISHED



(51) International Patent Classification 6 :

A61B 17/42

A1

WO 9602197A1

(43) International Publication Date: 1 February 1996 (01.02.96)

(21) International Application Number: PCT/NO95/00126

(22) International Filing Date: 11 July 1995 (11.07.95)

(30) Priority Data:

942636

13 July 1994 (13.07.94)

NO

(71)(72) Applicant and Inventor: SADEK, Latif [NO/NO]; Hamar Sykehus, N-2300 Hamar (NO).

(74) Agent: ONSAGERS PATENTKONTOR AS; P.O. Box 265 Sentrum, N-0103 Oslo (NO).

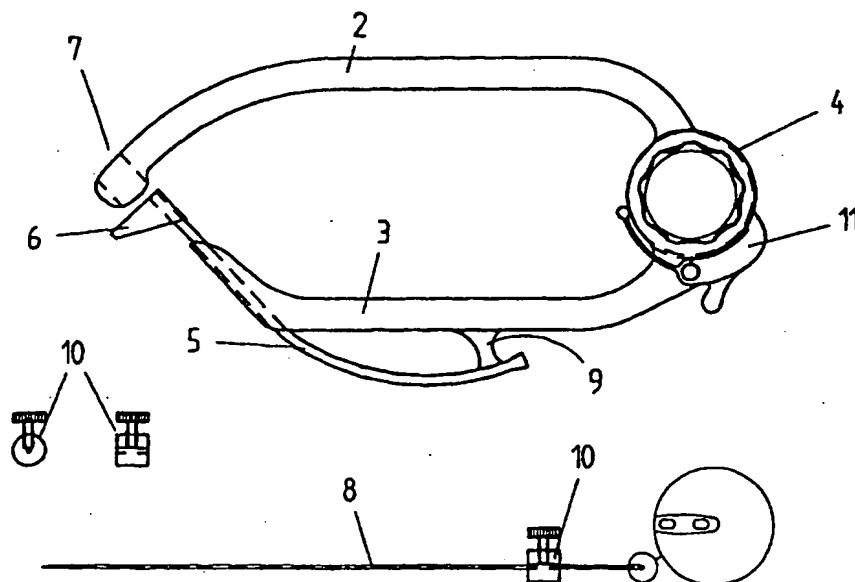
(81) Designated States: JP, NO, US, European patent (AT, BE, CH, DE, DK, ES, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE).

Published

With international search report.

In English translation (filed in Norwegian).

(54) Title: INSTRUMENT FOR GYNAECOLOGICAL SURGERY IN WOMEN



(57) Abstract

A surgical device consisting of two curved arms (2; 3), held together by a movable joint (4). One arm has in the end one or more elongated holes and when the device is closed the holes form an extension to the tube(s) on the other arm. The device can be opened by freeing teeth in the ratchet (11) from the teeth in element (4) and it is shut and locked automatically in a position where the holes in one arm complete the extension of the tubes in the other arm. The device also comprises a thin long needle(s) which in use will be guided through the tube(s) in one of the arms, and a movable needle holder (10). The instrument has several uses e.g. needle suspension for incontinence or prolapse.

FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AT	Austria	GB	United Kingdom	MR	Mauritania
AU	Australia	GE	Georgia	MW	Malawi
BB	Barbados	GN	Guinea	NE	Niger
BE	Belgium	GR	Greece	NL	Netherlands
BF	Burkina Faso	HU	Hungary	NO	Norway
BG	Bulgaria	IE	Ireland	NZ	New Zealand
BJ	Benin	IT	Italy	PL	Poland
BR	Brazil	JP	Japan	PT	Portugal
BY	Belarus	KE	Kenya	RO	Romania
CA	Canada	KG	Kyrgyzstan	RU	Russian Federation
CF	Central African Republic	KP	Democratic People's Republic of Korea	SD	Sudan
CG	Congo	KR	Republic of Korea	SE	Sweden
CH	Switzerland	KZ	Kazakhstan	SI	Slovenia
CI	Côte d'Ivoire	LI	Liechtenstein	SK	Slovakia
CM	Cameroon	LK	Sri Lanka	SN	Senegal
CN	China	LU	Luxembourg	TD	Chad
CS	Czechoslovakia	LV	Latvia	TG	Togo
CZ	Czech Republic	MC	Monaco	TJ	Tajikistan
DE	Germany	MD	Republic of Moldova	TT	Trinidad and Tobago
DK	Denmark	MG	Madagascar	UA	Ukraine
ES	Spain	ML	Mali	US	United States of America
FI	Finland	MN	Mongolia	UZ	Uzbekistan
FR	France			VN	Viet Nam
GA	Gabon				

Instrument for gynaecological surgery in women.

The invention relates to an instrument for use in the surgical treatment of gynaecological complaints.

5 The surgical treatment of incontinence and/or gynaecological prolapse in women is both expensive and complicated.

Out-patient treatment of incontinence or gynaecological prolapse should fulfil the following criteria:

1. The surgical technique should be as simple as possible.
2. Contacting the bladder with a surgical instrument should be avoided.
- 10 3. The surgical area should be as limited as possible to avoid the risk of bleeding.
4. It should be possible to perform the operation under local anaesthetic.

15 This can only be achieved by use of a thin needle, avoiding contact with the bladder or bladder neck (urethra) from above during surgery and making only minimal incision in the abdominal wall.

There are several types of instrument for surgical treatment of incontinence (US 5 149 329, US 5 013 292, US 5 112 344 and US 5 019 032).

20 Of these, US 5 112 344 concerns an instrument for correction of incontinence. This consists of a flexible needle plus a needle holder, while US 5 019 032 is a similar instrument which also has the facility for visually monitoring the operation. US 5 013 292 consists of a needle, cannula and sutures. US 5 149 329 consists of a pliable tube, a pliable suture needle with a cutting edge and a needle holder. The needle is pushed through the tube with the aid of the needle holder which has a fingergrip.

25 What is common to all these instruments is that they are constructed for a specific surgical technique and are not interchangeable. As an example the instrument in US 5 149 329 cannot be used with the present operating

technique because the needle is too short and thick, and the thickness of the needle increases the risk of bleeding and it will be impossible to use local anaesthetic. The needle cannot be inserted blindly without a considerable risk of damage to the other organs in the abdomen. None of the instruments used in the prior art can therefore be used in surgical treatment in accordance with the four above mentioned criteria.

The object of the present invention is therefore to present an instrument which can be used for surgical treatment fulfilling the above criteria.

This object is achieved by the present invention characterized by the enclosed claims.

The instrument is used for needle suspension of the bladder neck for treatment of women suffering from incontinence. The instrument can also be used to perform a new and simple surgical technique for women with second degree of prolapsed uterus and utero-vaginal prolapse or for total vaginal (Vault's vaginal) prolapse following an earlier hysterectomy. The use of the instrument is, however, not limited to these complaints.

The present invented instrument consists of a device 1, with two movable arms 2, 3, held together by a movable joint 4, with a spring tensioned ratchet 11. The movable joint 4 with ratchet 11 prevents the device from opening unless released by manually turning the ratchet 11 so that the teeth are disengaged. The lower arm 3 ends in a transverse ring 6, which fits on to a normal size finger. In addition arm 3 has one or more tubes 5 built into the arm, and the end opening of this or these is on the outer edge of the ring 6. Tube(s) 5 has (have) a gently curved form and the other end is fastened in arm 3 with a bracket 9. Upper arm 2 has in its tail end one or more oblong holes 7 so that when the device is shut it corresponds with the openings of the tubes 5 at the ring's outer edge 6. In addition the instrument contains one or more thin needles 8 which are sharp (cutting) in one end and blunt in the other and where one or more holes are positioned, side by side lengthwise which are of suitable diameter for double surgical thread. The needle(s) will in use be guided through a tube 5 and must therefore be made of slightly pliable material. When the needle is in use the needle holder 10 should be employed. This has a suitably sized hole through it and a screwclamp to retain the needle.

The invention is described in more detail with the help of the drawings where:

Fig. 1 shows a sideview of a closed device,

5 Fig. 2 shows the needle holder and the needle with the holes in the blunt end enlarged,

Fig. 3 shows a sideview of the device with the movable connecting link dissembled and the arms removed, and

Fig. 4 shows a sideview of the bracket closed and a cross section of the device seen against the line V-V'.

10 Use of the instrument is initiated by opening the device, and inserting arm 3 into the vaginal opening, guiding it with a finger placed in ring 6, so that the end(s) of tube(s) 5 on ring 6 is (are) placed against a small lateral cut in the vagina. The top end of arm 2 is placed in a small skin cut above the symphysis and at the side of the middle line. When arm 2 and 3 are correctly
15 positioned, the device will automatically lock with the ratchet 11 in the movable connecting link 4. The hole(s) 7 on arm 2 are now positioned over the end(s) of tube 5 in arm 3. Needle 8 is inserted into needle holder 10 and fastened with the needle holder screw, then inserted through tube 5 so that it penetrates connective tissue and muscle tissue in the abdominal wall and
20 passes through hole 7 in arm 2. The ratchet 11 now releases the movable connecting link 4 so that the device opens and can be pulled out. This leaves needle 8 in the abdominal wall with the blunt end, with the holes protruding from the vaginal opening and the sharp end sticking up through the skincut above the symphysis. The bladder is viewed from the inside by cystoscopy
25 to ensure that needle 8 does not penetrate the bladder. If this should happen, the needle 8 must be withdrawn, repositioned and checked again. The threads from one stitch or more which have been made in the vaginal wall can now be inserted through the holes in needle 8 and pulled up through the abdominal wall with the help of the needle. Several holes in needle 8 make
30 it possible to keep apart the thread ends which are being pulled out. The neck of the bladder or the vaginal wall or possibly the uterus, can now be lifted up by fastening the thread ends in a band in the abdominal wall. The skin cut and the cut in the vagina should now be closed by sutures. Some

patients have the need for several fastening points in the abdominal wall. This can be effected by using several tubes 5, all ending side by side which makes it possible to place several needles 8 at the same time while the device is in place. The design of the instrument makes this possible.

- 5 Fig. 1 describes the invention where the upper curved arm 2 has one, normally two, elongated holes 7 which are placed squarely across the arm so that they effectively lengthen the tube(s) when the device is shut. The upper arm 2 is connected by a movable connecting joint 4 with a spring tensioned ratchet 11. These connections are so placed that when the device is shut the
10 holes 7 will always be positioned virtually above the tube openings 5 in ring 6, with minimal lateral leverage. The lower arm 3 is also curved so that when viewed from the side the device is almost oval. This distal part of the arm 3 ends in a ring placed across 6 which in its edge has one or more, (usually two) end openings for the tube(s) 5, whose openings are positioned
15 against the holes 7 in arm 2 when the device is shut. The ring 6 is gauged to the diameter of a normal finger. The tube or tubes 5 which are rigid structures and are made of the same material as the arms 2 and 3 can be built into parts of arm 3 or be lying free on the outside of the arm. They must not however, be more curved than that the needle 8 can be drawn through the
20 tube without difficulty.

- Fig. 2 shows the needles 8 which are sharp (cutting) at one end and blunt with two holes positioned side by side lengthwise at the other end. Other models may have several holes. The needles match the inner diameter of the tube 5 and may be made of a pliable material for example a steel alloy. A
25 needle holder 10 with holes can be pulled on to the needle and fastened onto this with a screw clamp.

- Fig. 3 shows the device 1 with movable joint disassembled. The movable joint consists of the element 4a on arm 2 with teeth in the outer edge and 4b on arm 3 where the ratchet 11 is attached and movable so that the spring loaded
30 ball presses against the element 4b. The movable joint can be released, and the ratchet's "toothed" end disengaged by pressing the "tongue" of the ratchet against arm 3.

Fig. 4 shows a side view of the closed device as in Fig. 1 and a cross section through line V-V', showing the formation of holes 7. These can have any

suitable shape but are usually elongated and make up the continuation of tube 5 when the bracket is shut.

5 In one embodiment of the invention the whole device 1 is made of the same material, e.g. hard plastic or a metal such as a steel alloy, while in another embodiment the arms 2, 3 are made of rigid plastic for single use (disposable), while the movable joint is made of metal for re-use. The arms 2, 3 are in this case connected to the movable joint with the aid of a single, rigid connection of known type.

The advantages of the instrument

- 10 1. Correct placing of the device avoids the risk of touching or damaging other organs.
2. During the passage of the needle, the needle meets the holes 7 in arm 2 and passes out without the need for further palpation by the surgeon's finger from above, which could risk damage to the finger. This protects
15 both the surgeon and the patient against transmittable blood diseases.
3. The instrument has several areas of use;
- Needle suspension for stress incontinence;
 - Needle suspension for treatment of uterovaginal prolapse or Vault's vaginal prolapse which occasionally happen after removal of the
20 uterus.

Operation advantages

1. An alternative for patients with unsuccessful results after the traditional operation with its recurrent failure risk.
- 25 2. The operation protects and improves the sex life of women with prolapse.
3. Simple to perform.
4. Performed under lumbar or local anaesthetic.

5. Short operating time.

6. Minimal bleeding during operation.

5 We have achieved good results in the two types of operation where the recovery percentage is 94,1 for urine incontinence when examined after 14,2 months and 90% for gynaecological prolapse examined after 12 months.

PATENT CLAIMS

1. Surgical device for use in gynaecological operations, characterized in that it comprises
(A) device (1) which consists of two curved arms (2, 3) made of suitable material, which is held together by a movable joint (4) with a ratchet (11), in one end of the arm (2, 3) made of the same or other material, while arm (2) has in the other end one or more elongated holes (7) running at 90 degree angle to the length of the arm, so that when the device is closed the holes form an extension to the tube(s) (5) on arm (3) which emerge(s) in the outer edge of the ring (6) which is positioned transversely with the other openings of the tubes firmly fastened to the arm (3) by a bracket (9), so that the device can be opened by freeing the teeth in the ratchet (11) from the teeth in the element (4a), and that it shuts and is locked automatically in a position where the holes (7) complete the extension of the tubes (5);
(B) a thin, long needle (8) made of suitable material which has a sharp edge in one end and one or more holes side by side in the blunt end, and
(C) a movable needle holder (10) pierced by a hole suited to the needle (8) where the needle (8) can be fastened by a screwing device when the needle holder is fitted onto the needle.
2. Surgical device according to claim 1, characterized in that arm (2) has two oblong holes side by side and arm (3) has two tubes (5) side by side.
3. Surgical device according to one of the preceding claims, characterized in that the tubes (5) are at least partly built into the arm (3).
4. Surgical device according to one of the preceding claims, characterized in that the arms (2, 3), movable joint (4), ratchet (11) and tubes (5) are made of the same material, e.g. rigid plastic or steel alloy.
5. Surgical device according to one of the preceding claims, characterized in that the movable joint (4) is made of metal for re-use while the arms (2, 3) and the tubes (5) are made of rigid plastic for single use only and attached to the movable joint by a rigid joint (12).

6. Surgical device according to one of the preceding claims, characterized in that the needle (8) is made of a stainless steel alloy.

1/2

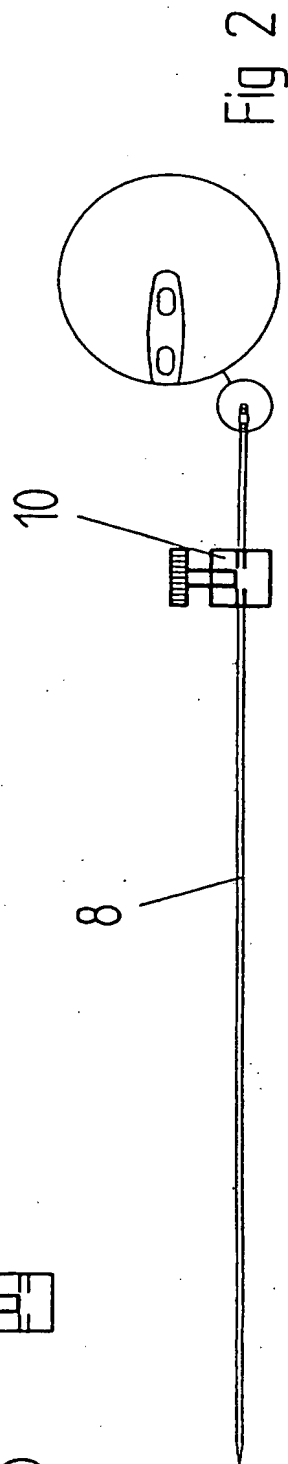
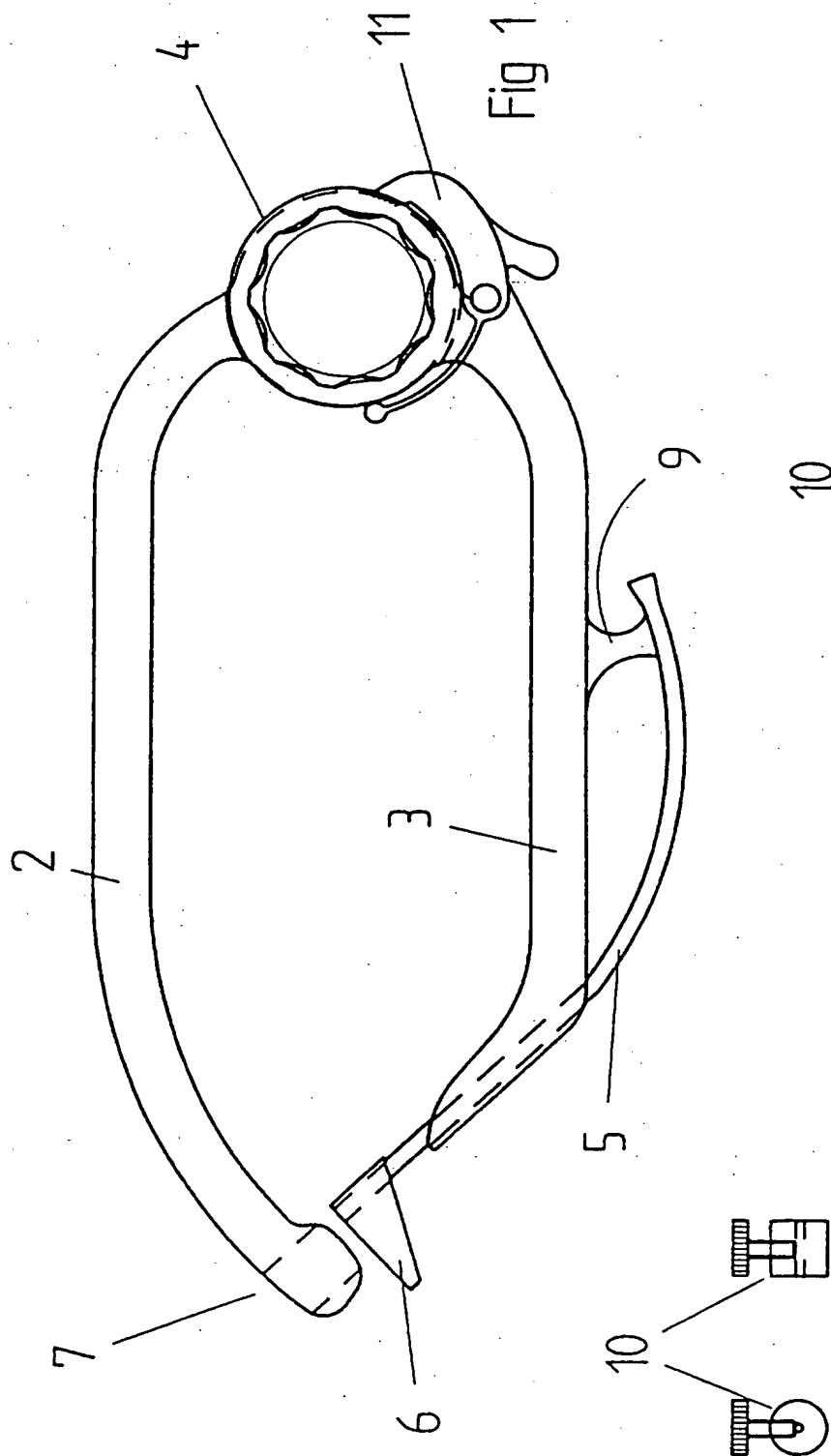
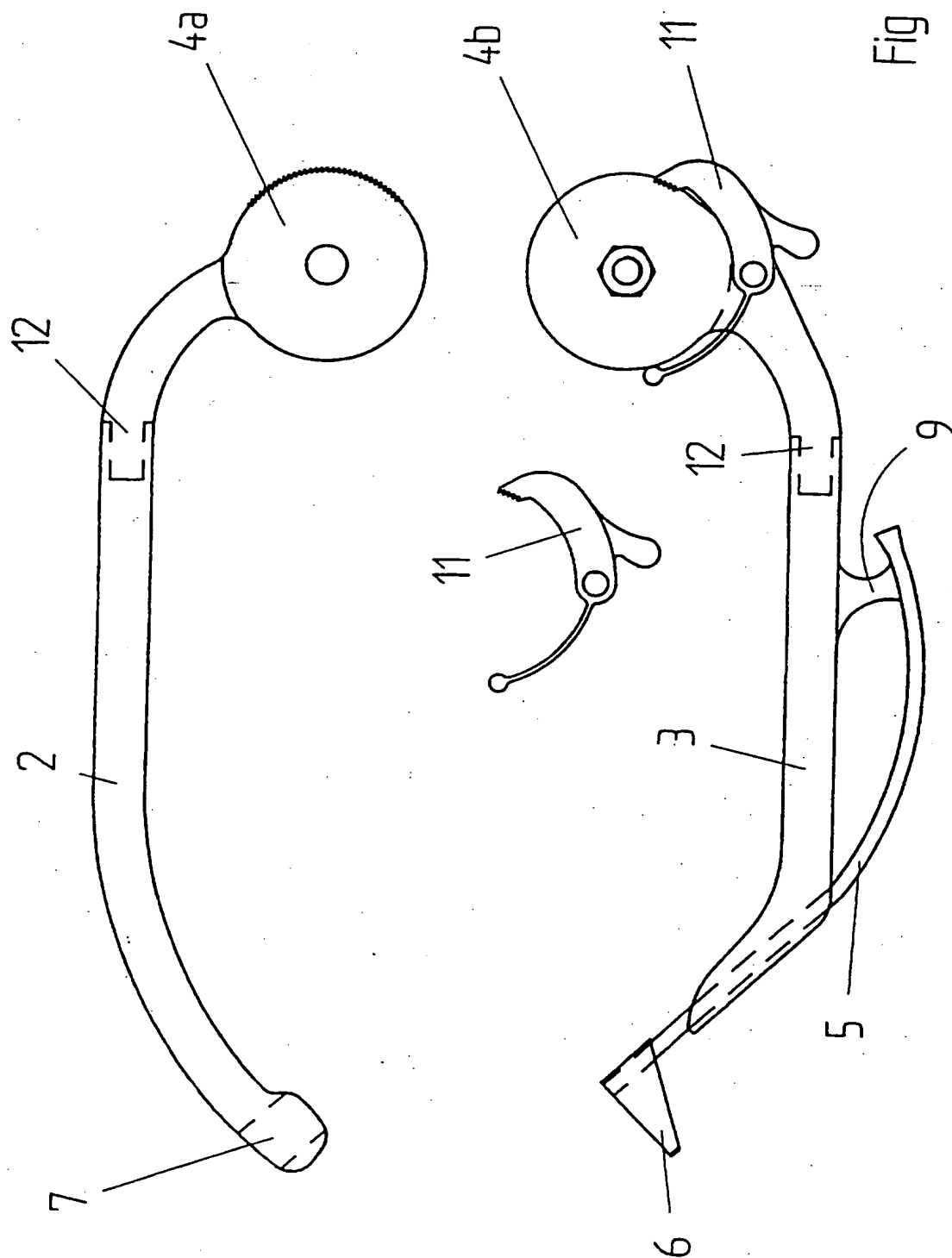


Fig 3



INTERNATIONAL SEARCH REPORT

International application No.

PCT/NO 95/00126

A. CLASSIFICATION OF SUBJECT MATTER

IPC6: A61B 17/42

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC6: A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

SE,DK,FI,NO classes as above

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

EPODOC, MEDICINE DATABASES ON DIALOG

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	WO 9003766 A1 (PETROS, PETER, EMANUEL), 19 April 1990 (19.04.90), abstract, claims --	1-6
A	WO 9319678 A2 (VESITEC MEDICAL, INC.), 14 October 1993 (14.10.93), abstract --	1-6
P,A	THE JOURNAL OF UROLOGY, Volume 152, 1994, Theodore V. Benderev, "A Modified percutaneous outpatient bladder neck suspension system", page 2316, the whole document -----	1-6

☐ Further documents are listed in the continuation of Box C.☒ See patent family annex.

* Special categories of cited documents:

- * "A" document defining the general state of the art which is not considered to be of particular relevance
- * "E" earlier document but published on or after the international filing date
- * "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- * "O" document referring to an oral disclosure, use, exhibition or other means
- * "P" document published prior to the international filing date but later than the priority date claimed

* "T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

* "X" document of particular relevance: the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

* "Y" document of particular relevance: the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

* "&" document member of the same patent family

Date of the actual completion of the international search

2 November 1995

Date of mailing of the international search report

07-11-1995

Name and mailing address of the ISA/
Swedish Patent Office
Box 5055, S-102 42 STOCKHOLM
Facsimile No. +46 8 666 02 86

Authorized officer

Agneta Österman Wallin
Telephone No. +46 8 782 25 00

INTERNATIONAL SEARCH REPORT

Information on patent family members

02/10/95

International application No.

PCT/NO 95/00126

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO-A1- 9003766	19/04/90	AT-T- 119758 AU-A- 4406489 DE-D,T- 68921762 EP-A,A,B 0437481 SE-T3- 0437481 US-A- 5112344	15/04/95 01/05/90 03/08/95 24/07/91 12/05/92
WO-A2- 9319678	14/10/93	NONE	